

Section 3, Part A: Prevention for Individuals Living with HIV and Their Sex or Injecting Drug- Using Partners Who Are HIV Negative or Unaware of Their HIV Status

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF PREVENTION CASE MANAGEMENT (PCM) FOR PERSONS LIVING WITH HIV

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF PCM FOR PERSONS LIVING WITH HIV

Prevention Case Management (PCM) is a client-centered HIV prevention activity with the fundamental goal of promoting the adoption and maintenance of HIV risk-reduction behaviors by clients with multiple, complex problems and risk-reduction needs.^{1,2} PCM provides client-centered, multiple-session HIV risk-reduction counseling to help individuals initiate and maintain behavior change to prevent the transmission of HIV while addressing competing needs which may make HIV prevention a lower priority. This HIV prevention activity addresses the relationship between HIV risk and other issues such as substance abuse, mental health, social and cultural factors, and physical health.

As a hybrid of HIV risk-reduction counseling and traditional case management for people living with HIV (PLWH), PCM provides intensive, on-going, individualized prevention counseling, support, and service brokerage. Priority for PCM services should be given to HIV seropositive persons having or likely to have difficulty initiating or sustaining practices that reduce or prevent HIV transmission and reinfection. PCM involves the coordination of primary and secondary prevention interventions and often involves close collaboration with Ryan White CARE Act (RWCA) case management providers. PCM services might include traditional risk-reduction topics such as abstinence, decreasing the number of sexual/needle-sharing partners or increasing condom use, as well as other subjects including medication adherence or taking an active role in medical care. Further, PCM ensures referral to needed medical and psychosocial services affecting risk behavior, including mental health and substance abuse treatment services as well as diagnosis and treatment of sexually transmitted diseases (STDs).

CORE ELEMENTS, KEY CHARACTERISTICS AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. PCM has 6 core elements which include:

- 1) PCM is a hybrid of HIV risk-reduction counseling and traditional case management.
- 2) PCM is based on the premise that some people may not be able to prioritize HIV prevention when they face problems perceived to be more important and immediate.
- 3) PCM is intended for people living with HIV (PLWH) with multiple, complex problems and risk-reduction needs who are having, or are likely to have difficulty initiating or sustaining practices that reduce or prevent HIV transmission.
- 4) Individuals who are committed to participating in ongoing risk-reduction counseling should be targeted with PCM.
- 5) Organizations must hire case managers with the appropriate training and skills to complete the PCM activities within their job description.
- 6) Clear procedure and protocol manuals for the PCM program must be developed to ensure effective delivery of PCM services and minimum standards of care.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. PCM has 8 key characteristics:

- Develop a client recruitment and engagement strategy.
- Screen and assess clients to identify those who are at highest risk and are appropriate for PCM.
- Develop a written, client-centered prevention plan.
- Provide multiple HIV risk-reduction counseling sessions.
- Provide active coordination of services with follow-up. Agency protocols should address co-managing clients with RWCA case managers to avoid duplication of services.
- Monitor and reassess clients' needs, risks, and progress.
- Establish protocols to classify clients as "active," "inactive," or "discharged," and outline the minimum active effort required to retain clients.
- Discharge clients from PCM upon attainment and maintenance of risk reduction goals.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for PCM follow:

When a new client is introduced to the PCM program, providers should ensure that the reason for the referral, the role of the PCM program, and the role of the provider are understood. Written, informed consent describing all relevant policies and procedures (including the confidential and voluntary nature of the service) and a commitment to participate in ongoing risk-reduction counseling should be obtained. Clients should be provided a copy of this consent, and the original should be maintained in an individual client record. Each client should have an

individual confidential file, and all records should be kept in a locked file cabinet with access limited to the prevention case manager and his/her immediate supervisor.

All clients must be screened for eligibility for services. Appropriate screening procedures should be developed to identify persons at highest risk for transmission or acquisition of HIV. Assessment instruments should address HIV and STD transmission risks, substance use/abuse, and medical and psychosocial needs. Care should be taken to ensure that the assessment is conducted in a culturally appropriate manner.

After completion of the assessment, the PCM provider and the client should collaborate on the development of a prevention plan which is then signed by the client and provider. The plan should outline and define risk-reduction behavioral objectives and strategies for behavioral change. In addition to risk reduction goals, the plan for HIV-positive clients should include referral to appropriate medical care if needed and should address adherence to retroviral medication, if appropriate. PCM providers should coordinate with the RWCA case manager, where possible to provide the best possible constellation of services. The plan must also include referral for evaluation and treatment of STDs, TB, hepatitis and other related health concerns at regular intervals. It should address referral for substance abuse treatment, if necessary. Partner counseling and referral services (PCRS) should also be addressed in the prevention plan. Finally, plans for referral follow-up should be outlined.

When risk behaviors have been identified and appropriate risk-reduction strategies have been outlined, prevention case management sessions begin. Multiple counseling sessions are aimed at meeting the identified behavioral objectives. These sessions may include education, skill development, role-play, support, or other techniques. Client notes should be filed after each session indicating, at a minimum, the goal addressed during the session, progress toward the goal, barriers to implementation of behavior change and the way these are or will be addressed, referrals made with plans for follow-up, and a plan for the next session.

PCM providers should ensure active coordination of services with follow-up to avoid duplication of services (e.g., agency protocols should address co-managing clients with RWCA case managers). If referrals are to be made as a part of the prevention plan, the agency should have a standardized written referral process. A system should be in place to ensure availability and access to these referrals and to track their completion. This system might include formal or informal agreements including memoranda of agreement with relevant service providers. Written informed consent from the client for sharing client information should be obtained before communication between agencies begins. Medical and psychological services should be available if emergencies arise, and referral agreements for these services should be in place before initiating PCM. Current referral and access information for all community providers should be maintained.

Ongoing needs assessment is essential to monitor progress toward PCM goals and to monitor changing needs of the client. Prevention plans must be updated to reflect any change. Upon attainment and maintenance of the objectives of the plan, a determination should be made by the client and the PCM provider that the client is ready for discharge from PCM. Agencies

implementing PCM must have discharge protocols in place to ensure that discharged clients are connected to needed services and resources, and a return to PCM is available, if needed.

RESOURCE REQUIREMENTS

Because PCM is an intervention with a great deal of overlap with mental health services, providers must have experience in managing mental health issues (a licensed counseling or mental health provider is preferred). Staffing levels for PCM will vary according to the number of clients that an agency expects to serve and the availability of other services in the area. In areas with limited referral sources, the PCM provider will be expected to meet multiple needs for his/her clients. To meet these needs, it will be necessary to reduce the case load for individual providers. In resource-rich areas, more service needs can be met by referral and a PCM provider can be expected to carry a larger caseload. Programs should consider the number of clients to be served, the needs of those clients and the services available in their area when determining staffing levels needed, but a typical caseload will include approximately 15-20 clients for each 1.0 full-time equivalent (FTE) PCM provider.

RECRUITMENT

PCM programs rely upon referrals and recruitment to establish a client base. To enlist clients for PCM, programs should be located in a setting that offers other services for PLWH. In this setting, clients can be referred from existing services that the program offers, such as outreach, counseling and testing services, Ryan White case management, medical care, STD assessment and treatment, substance abuse treatment, or mental health services to PCM. If these services are not offered on site, referral agreements from agencies providing these services should be established. Incentives (e.g., bus tokens, hygiene kits, t-shirts) can be used to increase participation.

Agencies wishing to implement PCM should review the Procedural Guidance for Recruitment (see p. 11) in order to choose a recruitment strategy that will work in the setting in which they plan to implement PCM.

PHYSICAL SETTING CHARACTERISTICS

Agencies implementing PCM should choose a location that is easily accessible from public transportation routes. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room, or outside noise levels. It may be necessary for providers to meet clients outside of an office setting. In this case, efforts should be made to secure a location that will ensure the confidentiality of the client and minimize distractions and interruptions. Regardless of where actual PCM sessions occur, the agency implementing the intervention must ensure that all records are maintained in a locked file cabinet or in a secured computer workstation.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement PCM the following policies and procedures should be in place to protect participants, the agency, and the Prevention Case Manager:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that PCM is an intervention that deals with disclosure of HIV status. Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior. All persons screened for PCM, regardless of eligibility, should be offered counseling by a prevention case manager and referrals relevant to their needs.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both providers and participants should be in place when implementing PCM:

Provider: Providers of PCM services should have experience working in the fields of mental health services and HIV prevention (a licensed counseling or mental health provider is preferred). Agencies should have in place a mechanism to ensure that all sessions address the prevention plan. Quality assurance activities can include observation or review of sessions with key staff and supervisors involved with the activity. This review should focus on the quality of and appropriate adherence to the prevention plan, accessibility and responsiveness to expressed client needs, and important process elements (e.g., time allocation, clarity). PCM providers should meet at least monthly with either a direct supervisor or with a peer supervisor. Selected intervention record reviews should focus on ensuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at regular intervals established by the agency. Process monitoring systems should also track the number of sessions each participant attends, as well as reasons for non-attendance.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:

- **I.C-** Proportion of persons that completed the intended number of sessions for each of the following interventions: individual level interventions (ILI) and group level interventions (GLI).
- **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
- **III.C** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
- **IV.A** Proportion of client records with the CDC-required demographic and behavioral risk information.
- **V.A** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

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U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

U.S. Department of Health and Human Services. *HIV Counseling, Testing, and Referral Standards and Guidelines*. May 1994.

U.S. Preventive Services Task Force. (1996). *Guide to Clinical Preventive Services*. Second Edition. Williams & Wilkins: Baltimore.

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UCSF, AIDS Policy Research Center, Prevention with Positives Resources

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF INTEGRATING PREVENTION SERVICES INTO MEDICAL CARE FOR PEOPLE LIVING WITH HIV

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF THE INTERVENTION

After testing positive for HIV, many people decrease behaviors that may transmit HIV to others.^{1,2} However, recent studies suggest that such behavioral changes are not maintained by all HIV-infected persons and that some continue to engage in behaviors that place others at risk for HIV infection.^{3,4} The HIV outpatient clinic is an ideal, yet underutilized, setting to (a) reach a large number of seropositive individuals who regularly visit the clinic for treatment; (b) implement a safer-sex prevention program to instill self-protective and partner-protective motivations for reducing risk behaviors across time; (c) integrate prevention with routine medical care; and (d) involve clinic staff, especially physicians, physicians assistants, nurses, nurse practitioners, and counselors, in prevention counseling. Recognizing the importance of including HIV prevention in the medical care setting, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the National Institutes for Health (NIH), and the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA) recently published recommendations for incorporating HIV prevention into the medical care of persons living with HIV.⁵

The CDC/HRSA/NIH/HIVMA of the IDSA recommendations state that clinicians can greatly affect patients' risks for transmission of HIV to others by:

- Performing a brief screening for HIV transmission risk behaviors
- Communicating prevention messages
- Discussing sexual and drug-use behavior
- Positively reinforcing changes to safer behaviors
- Referring patients for such services as substance abuse treatment
- Facilitating partner notification, counseling, and testing
- Identifying and treating other sexually transmitted diseases (STDs)⁵

These recommendations are integrated into three major components:

- Screening for HIV transmission risk behaviors and STDs
- Providing brief behavioral risk-reduction interventions in the office setting and referring selected patients for additional prevention interventions and other related services

- Facilitating notification and counseling of sex and needle-sharing partners of infected persons⁵

The recommendations for incorporating prevention services into medical care are intended for all persons who provide care services to people living with HIV (PLWH) (e.g., physicians, nurse practitioners, nurses, physician assistants). This also includes, and would be appropriate for community-based organizations (CBOs) that provide medical care services. However, CBOs that do not provide care may choose to partner with care providers to offer a range of services including brief prevention messages delivered by the care provider as well as more traditional prevention services (e.g., Prevention Case Management, Partner Counseling and Referral Services, Counseling Testing and Referral for partners) that could be available on-site at the clinic.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's or strategy's intent and design and that are thought to be responsible for its effectiveness. Consequently, they must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention or strategy is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Integrating prevention into medical care has 7 core elements that include:

- 1) Adopt prevention as a standard part of clinical practice.
- 2) Conduct a brief assessment (risk screening) of behavioral and clinical factors associated with transmission of HIV and other STDs.
- 3) Identify patients at greatest risk for transmission of HIV who should receive more in-depth risk assessment and HIV risk-reduction counseling, other risk-reduction interventions, or referral for other services.
- 4) Deliver brief (3-5 minute) prevention messages focused on self and/or partner prevention and HIV status disclosure to every patient at every clinic visit.
- 5) Screen for and treat STDs, as appropriate.
- 6) Discuss reproductive health options with female patients of childbearing age.
- 7) Hang waiting and exam room posters and hand out patient brochures that present education and prevention messages and reinforce messages delivered by the clinician.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations to meet the needs of the target population and ensure cultural appropriateness of the strategy. Integrating prevention into medical care has 5 key characteristics:

- Screening methods include probing for behaviors associated with transmission of HIV and other STDs, eliciting patient reports of symptoms and other STDs, and laboratory testing for other STDs.
- Training for all clinic staff should include information on the use of open-ended questions, demonstrating empathy and remaining non-judgmental.
- Counseling sessions can last longer than 5 minutes and follow-up reminders may last less than 3-5 minutes depending on the needs of the patient. It is important to repeat the message over time.
- Providers need to deliver prevention messages at all clinic visits; however, these messages may be eliminated if pressing medical needs take priority.
- Clinics should make condoms available in a way that patients can feel comfortable taking them as needed.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for integrating prevention into medical care follow.

Incorporating prevention into a busy clinic can be difficult, but can be facilitated with some modification of the clinic structure and flow. Creating an atmosphere that endorses an integrated approach demonstrates that prevention of HIV is important to the clinicians and staff. Posting prevention messages in the waiting area and in examination rooms and giving every patient printed material related to HIV prevention reminds the clinician to address prevention, and prepares the patient to discuss these issues.

Prescreening patients prior to the medical appointment using pencil-and-paper surveys, audio-, video-, or computer-assisted questionnaires, or brief interviews with non-medical staff can provide the clinician with information that he/she can use to understand patients' risk factors and symptoms of STDs, if present, and to elicit more in-depth discussions of HIV prevention during the medical visit. If the patient reports engaging in risky behaviors (unsafe sex or injection practices) the clinician should provide an appropriate brief prevention message. This message may include a general prevention message, a tailored message which addresses specific patient behaviors or concerns, and messages that correct misconceptions about risk or reinforce steps the patient has already taken to decrease the risk of HIV transmission. Prevention messages should stress to patients that abstinence or sex with a partner of concordant serostatus are the only ways to ensure that HIV is not transmitted. However, patients should also know that sex with concordant partners does not protect against other STDs or reinfection with HIV. For sexually active patients, condom use is the safest means of preventing transmission or acquisition of HIV or other STDs. Patients should also be made aware of the importance of disclosure of their HIV status to potential sex partners.

Because the presence of an STD can dramatically increase the transmissibility of HIV and the progression of HIV disease, the clinician should also recommend diagnostic testing and treatment, as appropriate, for STDs for patients engaging in unsafe sexual behaviors. These tests should be recommended at the first visit for all patients, at least yearly for sexually active patients, and more frequently for patients at high risk. Patients should receive testing for STDs if

they report any symptoms of infection, regardless of reported sexual behavior or other epidemiologic risk information.

In addition, because the risk for perinatal HIV transmission is high without appropriate intervention, clinicians should assess whether women of childbearing age might be pregnant, are interested in becoming pregnant, or are not specifically considering pregnancy, but are sexually active and not using reliable contraception. Referral for reproductive health issues and counseling may be appropriate.

The clinician should also refer the patient for more extensive prevention intervention or to other services that may benefit the patient and/or his or her partner as needed (e.g., substance abuse treatment services, mental health services, medication adherence counseling, PCRS). Referral follow-up can provide the clinician with information about the success of the referral, patient satisfaction with the referral, or barriers to completing it. This information can be used to compile a referral guide for use by all clinic providers.

Finally, clinicians should recognize that risk is not static. Patients' lives and circumstances change, and their risk of transmitting HIV may change from one medical encounter to another. Screening and providing risk-reduction messages should occur at every medical visit unless pressing medical issues take precedence.

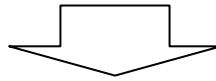
Materials that are helpful for introducing the concept of integrated prevention and care services include:

- *Posters*, in languages appropriate to the populations served, with the general prevention messages to hang in clinic waiting areas and hallways
- *Brochures*, in languages appropriate to the populations served, given to patients when they register at the front desk. The brochures should emphasize the role of STDs in HIV transmission and the need to be tested and treated for STDs at the first sign or suspicion of symptoms, the potential role of drug use in increasing risky behaviors, the risks of unsafe sex or injection practices for patients and their partners even in the presence of a low or undetectable viral load, as well as messages about the importance of disclosure.
- *Exam room posters*, in languages appropriate to the populations served, which contain the same messages as the brochure.
- *Documentation of patient counseling* which may include such methods as a chart sticker, a stamp, or a check box in the printed or electronic medical record. The purpose is to remind the provider to do the counseling regularly.
- *Additional supportive materials* given out as a supplement to the brochure at subsequent visits. Materials can address additional prevention topics of interest, and may include helpful information and testimonials related to changing behavior.

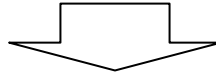
One model for integrating prevention into care is diagrammed below.

Patient is given a language appropriate brochure or flyer by front desk staff and asked to read it before seeing the medical provider. Patient reads the materials while waiting

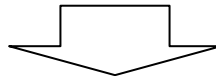
and notices the prevention posters in the waiting room.



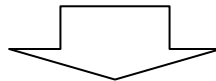
Patient goes into exam room and notices a small poster on the exam room wall that reinforces the messages that are in the brochure.



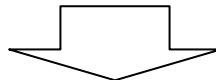
Provider conducts the usual medical exam.



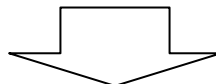
At the end of the medical exam the provider conducts a brief 3-5 minute intervention. Provider reviews the information gained in the pre-appointment survey and asks clarifying questions. Provider gives a brief prevention message targeted to the needs of the patient.



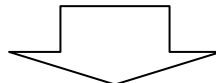
Provider uses the brochure, exam room poster, or other prevention materials to facilitate counseling. Provider or patient checks behaviors noted in the brochure and sets goals for behavior change. Provider documents counseling in the patient's chart.



If needed, the provider gives appropriate referrals to the patient. Provider tells patient that he/she is interested in hearing how it is going next time the patient comes in for an appointment.



Patient leaves feeling cared about, better informed about safer sex and disclosure practices, and motivated to practice safer behaviors.



For follow-up visits, provider inquires about progress on goals set and referrals, if given at last visit. Provider reinforces healthful behavior and helps patient find ways to overcome obstacles. Provider and patient re-establish goals for next time.

CBOs that do not provide medical care can partner with a medical provider to assist with the creation of prevention messages and materials that are appropriate for the clinic setting, and with

training and prevention strategies for clinics. CBOs can also assist clinics in providing and facilitating referrals and by providing more extensive prevention services to those clients with additional prevention needs.

RESOURCE REQUIREMENTS

Integrating prevention into medical care uses existing providers and clinic staff and asks that providers spend 3 to 5 minutes discussing safer sexual behavior and disclosure with their patients during each clinic visit. No new staffing is required, although each clinic should appoint a nurse or physician assistant (0.5 full-time equivalent [FTE]) as a prevention coordinator to coordinate training and ensure that materials are available and staff are implementing the intervention. The major expenses to clinics are materials (e.g., training materials, posters, brochures, chart stickers, anatomical models, condoms, and lubricant) and release time for each provider and clinic staff to attend training.

RECRUITMENT

Because agencies who choose to integrate prevention into their medical care as recommended by the CDC/HRSA/NIH/HIVMA of the IDSA guidelines will offer prevention services as the standard of care in their clinics, no specific strategy for recruitment is endorsed; all clinic patients receive the intervention with appropriate messages delivered at each appointment. However, all patients should be informed that the clinic has adopted a model of integrated service so that they may make an informed choice regarding their attendance at the clinic.

PHYSICAL SETTING CHARACTERISTICS

Sites must be HIV-outpatient health care clinics. Sites should be those where there is clinic-wide support for this intervention, with a commitment to training in incorporating prevention messages, communicating with patients about sex and drug use behavior, understanding prevention interventions and factors related to risk behavior, and knowledge of community resources available by referral. Clinics should have private examination rooms where providers can talk confidentially with patients about their sexual behaviors.

NECESSARY POLICIES AND STANDARDS

Before a clinic attempts to integrate prevention into its medical care, the following policies and procedures should be in place to protect participants, and the clinic:

Informed Consent: All clinic patients should be informed that addressing issues of sexuality and HIV prevention is part of the standard of care at the clinic that integrates prevention into medical care. As with any patient care issues, they have the right to refuse treatment.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in this intervention, clients will be disclosing their HIV status. Agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that the confidentiality of clinic patients is maintained.

Data Security: Agencies must have a data handling policy that will ensure patient confidentiality and the confidentiality of chart notes and intervention reminders.

Cultural Competence: Agencies must strive to offer culturally competent services by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers when possible, or translation should be available, as appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care*, which should be used as a guide for ensuring cultural competency in programs and services

Referrals: Clinics must be prepared to supply appropriate referrals to patients, as necessary. Providers must know about referral sources for prevention interventions/counseling (PCM, PCRS, health department/CBO programs for prevention interventions with PLWH) if patients need additional assistance in decreasing risk behavior.

Clinic Support: Clinic management must demonstrate support for integrating prevention into care by:

- Encouraging staff attendance at one training related to providing prevention services (i.e., providing paid time off to attend, and promoting the training)
- Obtaining, distributing, and maintaining prevention materials
- Committing to patient counseling delivered by primary care providers, and allowing providers the time to deliver prevention messages at every visit

QUALITY ASSURANCE

Quality assurance activities for clinics, providers, and patients should be in place when integrating prevention into care to ensure fidelity to the core elements of the service. These include the following:

- 1) *Chart Audits* to ensure that providers are delivering and noting the delivery of prevention messages.
- 2) *Provider Surveys* to assess skill in eliciting behavioral information, providing prevention messages, attitudes and beliefs about the provider's role in delivering prevention messages, frequency of message delivery, and satisfactions with the intervention.
- 3) *Patient Satisfaction* should be monitored.
- 4) *Observation* of the clinic by the clinic coordinator to ensure that materials are maintained in the waiting room and exam rooms and that patient brochures and informational flyers are handed out to all patients.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report standardized process and outcome monitoring data consistent with CDC requirements
- Enter and transmit data for CDC-funded services on PEMS (Program Evaluation Monitoring System), a CDC-provided browser-based system, or describe plans to make a local system compatible with CDC's requirements
- Collect and report data consistent with CDC requirements to ensure data quality and security, and client confidentiality
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects, upon request

KEY ARTICLES AND RESOURCES

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² Allen S, Serufilira A, Bogaerts J, Van de Perre P, Nsengumuremyi F, Lindan C, Carael M, Wolf W, Coates T, Hulley S. Confidential HIV testing and condom promotion in Africa: Impact on HIV and gonorrhea rates. JAMA 1992;268:3338-43.

³ Centers for Disease Control and Prevention (CDC). Resurgent bacterial sexually transmitted disease among men who have sex with men — King County, Washington, 1997 – 1999. MMWR 1999;48:773-7.

⁴Crepaz N, Marks G. Towards an understanding of sexual risk behavior in people living with HIV: A review of social, psychological, and medical findings. *AIDS* 2002;16:135-49.

⁵CDC. Incorporating HIV prevention into the medical care of persons living with HIV: Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medical Association of the Infectious Diseases Society of America. *MMWR* 2003; 52(RR-12); 1-24.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF TEENS LINKED TO CARE

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF TEENS LINKED TO CARE

Teens Linked to Care (TLC)¹⁻⁴ is an effective intervention for young people (ages 13 to 29) living with HIV and is delivered in small groups using cognitive-behavioral strategies to change behavior. Manuals, training materials, and training in the conduct and supervision of the intervention will be available from University of California at Los Angeles. A complete copy of the TLC intervention is located at <http://chipts.ucla.edu/interventions/manuals/>.

The intervention is based on Social Action Theory,⁵ which emphasizes how contextual factors influence an individual's ability to respond effectively to stressful situations, solve problems, and act effectively to reach goals. This theory was chosen based on qualitative study and other intervention research with disenfranchised young people, a majority of whom were people of color.⁶⁻⁹

Antiretroviral therapies have extended the length and quality of life for people living with HIV. Therefore, there is a need for ongoing support for maintaining behavioral changes over time. This program is designed to be implemented over a long period of time or over a two-to-three-month period, depending on staffing constraints and participants' preferences. The program can be offered on an ongoing basis, with multiple points of entry (drop-in) for young people over time. Alternatively, the program can be linked to medical care appointments. For example, when agencies have scheduled all persons living with HIV on a specific day, the program can be delivered in conjunction with treatment. Finally, by offering a large number of sessions, the program allows young people to drop-into maintenance sessions without finding redundant content.

TLC consists of three modules, each of which consists of 8-12 sessions that are delivered in a general sequence, with flexibility as to delivery and scheduling of sessions and multiple points of entry into the ongoing program by participating young people. Each module is focused on a different behavioral outcome:

Module I: *Staying Healthy* targets health care utilization and health behaviors. The module has been shown to increase the number of positive lifestyle behaviors and use of positive action coping styles in young women, and use of the social support coping style in young people of both sexes.

Module II: *Acting Safe* addresses both sexual and drug-use-related transmission acts. Research indicates that young people who attended the intervention reported fewer partners, fewer HIV-negative partners, and fewer unprotected sex acts. Additionally, youth attending the intervention reported significant reductions in a weighted substance use index, prevalence of alcohol/marijuana use, and the use of illicit drugs.

Module III: *Being Together* focuses on improving quality of life. In research, group members reported decreases in feelings of distress, physical symptoms of distress, generalized anxiety, and fear-based anxiety.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Teens Linked to Care has 4 core elements, which include:

- 1) The delivery of three modules. Each focuses on a different set of outcomes and includes 8-12 sessions, described below in **Content** and **Format** and structured in the theoretical model, which includes:
 - a. Review of previous goals
 - b. Activity focused on skills or attitude development or knowledge acquisition
 - c. Reframing of negative behavior patterns
 - d. Reinforcement of desired behavior using incentives
 - e. Setting of new goals
- 2) Delivery of modules in highly interactive small groups.
- 3) Exercises in each session that are constructed to be meaningful personal experiences, leading to increased skills and development of the attitudes and knowledge needed to support the acquisition of new behaviors.
- 4) Individualized homework tasks assigned following each session.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. TLC has 4 key characteristics:

- Groups may have between 3 and 13 members.
- Small group participants of similar ages are ideal, but groups can be comprised of individuals of different ages. Facilitators should tailor messages appropriate to the age group attending and the levels of development.

- Each session contains approximately six exercises or different activities.
- Participants should attend all sessions of the intervention, with flexibility for participants to drop into particular sessions on their own schedule.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for Teens Linked to Care follow.

Sessions: While the process of change is the same in each session, the content differs between sessions and was based on findings from qualitative research into what young people living with HIV think is important.

The following is a list of session topics by module:

Content:

Staying Healthy:

- Sessions 1 & 2: I'm HIV Positive--Attitudes Towards Living with HIV and Exploring Future Goals
- Session 3: Disclosure--Should I Tell Others My Status?
- Session 4: Coping with Stigma
- Session 5: Wanting to Stay Healthy
- Session 6: How Do I Use Drugs and Alcohol?
- Session 7: What Am I Going to Do about Substance Abuse?
- Session 8: Preventing Re-infection
- Session 9: Staying Calm
- Session 10: Attending Health Care Appointments
- Session 11: Taking Prescribed Medications
- Session 12: Participating in Medical Care Decisions

Acting Safe:

- Session 1: Should I Protect Myself and My Partner?
- Session 2: Which Protection Methods and Sex Acts Are Best for Me?
- Session 3: Should I Tell My Partner I Am HIV-Positive?
- Session 4: Should I Try To Get My Partner to Accept Our Using Condoms?
- Session 5: Should I Refuse Unprotected Sex?
- Session 6: Establishing the Commitment
- Session 7: How Can I Stop Drug and Alcohol Thoughts?
- Session 8: How Can I Avoid External Triggers?
- Session 9: How Can I Avoid Internal Triggers?
- Session 10: How Can I Handle Anxiety and Anger?
- Session 11: How Can I Handle Drugs, Alcohol, and Sex?

Being Together:

- Session 1: How Can I Have a Better Quality of Life?
- Session 2: How Can I Reduce Negative Feelings?
- Session 3: Who Am I?
- Session 4: Is What I See the Real Thing?
- Session 5: What Direction Should I Follow?
- Session 6: How Can I Be a Good Person?
- Session 7: How Can I Get Wise?
- Session 8: How Can I Care about Others?

Format: A small group of HIV-positive young people meet regularly to provide social support, learn and practice new skills, and to socialize. At the beginning of each session, participants review their progress toward achieving their goals. Young people are complimented and compliment each other for trying to change their lives. In the middle of each session, facilitators focus participants on skill development, attitude formulation, knowledge acquisition, and/or reframing of previous dysfunctional behavior patterns. A series of fun activities are used to accomplish this goal. Participants may videotape themselves meeting a new friend, disclosing their serostatus, or brainstorming on how to get angry with a doctor without then receiving poor medical care. New goal-setting occurs at the end of each session, and compliments are shared by all group members.

Mechanism of Behavior Change: This program helps HIV-positive young people identify ways to improve their quality of life within specific areas, by setting new habits and daily social routines. Young people set goals around their health, their sexual relationships, drug use, and daily peace. Once goals are set, the group helps each person set realistic ways to meet these goals and helps to solve problems related to reaching the goals. The steps of problem solving include:

- 1) Determining what you want.
- 2) Identifying ways to get what you want.
- 3) Evaluating the best way to get what you want.
- 4) Practicing how to get what you want.
- 5) Trying to get what you want.
- 6) Reviewing how successful you were in reaching your goal.

Participants not only work on their own goals, but role-play assisting other young people to reach their goals (e.g., a new job, a change in their living arrangements, education, or social relationships). At the end of every TLC session, participants agree on the next week's plans to improve their lives. Improving the quality of life, meditation, and focused attention skills are part of TLC.

Summary: Every session in each of the three TLC modules establishes a routine to help participants confront a specific attitude or belief, address thoughts and feelings, and/or change a specific behavior. As such, community agencies that implement TLC must include the following core components in each session in order for the intervention to be effective:

- Participants **review previous goal.**
- Facilitator provides **engaging activities focused on: problem-solving, attitude formulation, knowledge acquisition, and/or skill development.**
- Facilitators help participants to **reframe negative behavior patterns.**
- Facilitators **reinforce desired behavior through use of incentives.**
- Participants **set a new goal.**

Materials used to deliver and/or reinforce the intervention include hand cards, tokens, a feeling thermometer, participant workbooks, and a facilitator manual. Most of these items are available for download at the intervention website (see the end of this section). Role playing is used to demonstrate the relevant concepts or issues.

RESOURCE REQUIREMENTS

The resources needed are contingent upon the number of people living with HIV who are served in the agency. For an agency serving up to 200 people living with HIV, a desirable staffing pattern for an agency would be to hire a program supervisor (50% full-time equivalent [FTE]) for the first year to train, supervise, and coordinate implementation during the first year. This person should have experience in behavioral theories of change and experience in conducting interventions with persons in small groups. For the program delivery, one option is to train all counselors within an agency in the model and to offer drop-in groups at several different times during a week for people living with HIV. One group would be offered at night, one during the day, and one during the weekend. Therefore, there needs to be flexibility in the staffing pattern, with full time staff who are willing to adjust their schedules to the needs of clients. Each small group will require about 25% FTE per week of a counselor to deliver the program. One full-time (or FTE) should be able to provide the program to 50-70 people living with HIV at any one time. The counselor or case manager delivering the program must also have skills in managing interactions within small groups and behavioral and cognitive-behavioral, skills-building approaches to interventions. The desirable staffing pattern is to train all counselors within a case management service or a counseling service and to utilize about 25% of each counselor's time to deliver the program (excluding supervisory time). A TV and a VCR will be needed to deliver the program, as well as small items such as condoms, demonstration models, and standardized program workbooks. Four trainings of four days each are needed for program supervisors at intervals of one to two months apart. These supervisors may then be charged with training all staff within the agency.

RECRUITMENT

Young people living with HIV can be recruited for TLC from a variety of sites: community venues, AIDS service organizations, or medical clinics. Young people can also be recruited through word-of-mouth, print advertisements, or flyers. Agencies wishing to implement TLC should review the Procedural Guidance for Recruitment (see p. 11) in order to choose a recruitment strategy that will work in the setting in which they plan to implement TLC.

PHYSICAL SETTING CHARACTERISTICS

TLC can be implemented at any location where the confidentiality of participants can be ensured (e.g., a private room) and an agency is able to assemble a group of young people living with HIV who wish to participate in the intervention.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement TLC the following policies and procedures should be in place to protect participants, the agency, and the TLC intervention team:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in TLC, clients will be disclosing their HIV status. With that in mind agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to

these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Prevention Case Management, Partner Counseling and Referral Services, Health Department/Community-based Organization programs for prevention interventions with PLWH) if clients need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both facilitators and participants should be in place when implementing TLC:

Facilitator: Training for facilitators should address the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practice of mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. QA activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of key cognitive behavioral skills techniques; accessibility and responsiveness to expressed participant needs; and important process elements (e.g., time allocation, clarity, use of social rewards). Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at the final session of each module. Process monitoring systems should also track the number of sessions each participant attends, as well as reasons for non-attendance.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **III.C-** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information

KEY ARTICLES AND RESOURCES

¹Rotheram-Borus MJ, Lee MB, Murphy DA, Futterman D, Duan N, Birnbaum J, and the Teens Linked To Care Consortium. (2001). Efficacy of a preventive intervention for youth living with HIV. *Am J Public Health*, 91, 400-405.

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³Rotheram-Borus, M.J. & Miller, S. (1998). Secondary prevention for youths living with HIV. *AIDS Care*, 10(1), pp.17-34.

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⁵Ewart C. (1991), Bandura A. (1994). Social action theory for a public health psychology. *Am Psychol.* 46(9), 931-946.

⁶Luna GC, Rotheram-Borus MJ. (1999). Youth living with HIV as peer leaders. *Am J Commun Psychol*, 27, 1-23.

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⁹Luna GC. (1997). *Young people living with HIV: Self-evident truths*. New York, NY: Hayworth: Plenum Press.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). *Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators*.

A complete copy of the TLC intervention is located at
<http://chipts.ucla.edu/interventions/manuals/>

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PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF HOLISTIC HARM REDUCTION PROGRAM

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF HOLISTIC HARM REDUCTION PROGRAM

The Holistic Harm Reduction Program (HHRP)¹ for HIV-positive injection drug users is a 12-session, manual-guided, group level program to reduce harm, promote health, and improve quality of life. Intervention materials including background information, and research, as well as manuals and instructional materials for individual and group sessions are available for download by clicking on the Training link at <http://www.3-S.us>.

The program is based on the Information, Motivation, Behavior (IMB) model of behavior change. The HHRP counselor manual was designed to be highly “user-friendly” as it contains both relevant background and theoretical material and detailed scripts for each session. This minimizes the need for extensive prior training. In this program, HIV-positive injection drug users are viewed as autonomous individuals responsible for making informed, personal choices concerning behaviors that pose varying degrees of risk to themselves and others. The primary goal of HHRP is to provide group members with the resources (i.e., knowledge, motivation, and skills) they need to make choices that reduce harm to themselves and others.

Because HIV-positive injection drug users may have unique medical and psychological problems that contribute to illicit drug use and other high-risk behavior, and which may include neuropsychological and/or psychiatric impairment, addressing these problems may help clients to make healthier lifestyle choices for health promotion. Therefore, in addition to providing substance abuse treatment, HHRP addresses medical, emotional, and social problems that may impede harm reduction behaviors, and uses cognitive-remediation strategies to improve knowledge, increase motivation, and teach skills needed for harm reduction and health promotion. In this setting abstinence from illicit drugs or sexual risk behaviors is seen as one of several treatment goals. These goals could also include reduced drug use, reduced risk of HIV transmission, and improved medical, psychological, and social functioning.

Finally, HHRP activities are designed to address clients as complex human beings in search of physical, emotional, social, and spiritual well-being. By including strategies such as relaxation training and respect for clients’ spiritual and religious beliefs, the program aims to assist clients in achieving serenity in the expression of their lives. This can lead to a reduction in behaviors that cause harm to self and others.

When compared to an Enhanced Methadone Maintenance Program (EMMP) which includes a 6-session HIV risk reduction component, participants in both the EMMP and HHRP groups

exhibited significant improvements on measures of addiction severity, harm reduction behaviors, harm reduction knowledge, motivation, behavioral skills, and quality of life. Members of the HHRP group had significantly greater improvement in behavioral skills and showed continued decreases in addiction severity and risk behavior after 3 months. Members of the control group did not maintain gains.

Intervention materials including background information, and research, as well as manuals and instructional materials for individual and group sessions are available for download by clicking on the Training link at <http://www.3-s.us/>.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. The Holistic Harm Reduction Program has 6 core elements which include:

- 1) HHRP is a 12-session, manual-guided group intervention for HIV-positive injection drug users with three primary treatment goals – harm reduction, health promotion, and improved quality of life.
- 2) HHRP's focus on harm reduction entails reducing drug use and other high-risk behaviors, including sharing of drug paraphernalia and unsafe sexual practices. Although abstinence from illicit drug use is a primary aim of treatment, patients who do not attain abstinence, but who reduce drug use and other harmful behaviors, are not considered treatment failures.
- 3) HHRP's focus on health promotion entails addressing medical, emotional, and social problems that may be associated with disease progression, and includes enhancing medication adherence, improving communication skills with health care providers, and becoming informed concerning basic health components.
- 4) HHRP's focus on improving quality of life entails respecting and drawing upon clients' spiritual and religious beliefs, helping clients cope with stigma and grief, teaching stress management techniques, and acknowledging and addressing fears of death and dying.
- 5) HHRP is guided by the IMB model. Each group provides patients with the information, motivation, and behavioral skills needed to attain and implement treatment goals in real world settings.
- 6) Because HIV-positive injection drug users may present to treatment with mild to moderate cognitive difficulties, HHRP utilizes easily administered, cognitive remediation strategies, such as behavioral games and visual presentation of material (e.g., slides). Behavioral games and visual presentation materials are included in the treatment manual

to help improve knowledge, increase motivation, and teach skills needed for harm reduction, health promotion, and improved quality of life.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. HHRP has 5 key characteristics:

- Group sessions are held at the same time and place each week and follow the same structured format.
- Groups include between 3 and 15 participants.
- Groups are co-facilitated by two substance abuse counselors with experience working with HIV-positive substance abusers and who are comfortable with the concepts of harm reduction in this population.
- The facilitation team should include one male counselor and one female counselor, if possible.
- At least one of the counselors co-facilitating the interventions should have a master's degree in a counseling discipline.

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for HHRP follow.

Sessions: The HHRP manual provides 12, two-hour group sessions that can be presented as 1 weekly two-hour session for 12 weeks (recommended); or 2 weekly one-hour sessions for 12 weeks, or 1 two-hour session alternating with discussion groups weekly for 24 weeks. The manual provides an individual treatment orientation session that can be provided prior to the client beginning group treatment.

Content: The 12 session topics include:

- Session 1: Setting and reaching goals
- Session 2: Reducing the harm of injection drug use
- Session 3: Harm reduction with latex
- Session 4: Negotiating harm reduction with partners
- Session 5: Preventing relapse to risky behavior
- Session 6: Health care participation
- Session 7: Healthy lifestyle choices
- Session 8: Introduction to the 12-step program
- Session 9: Overcoming stigma
- Session 10: Motivation for change: overcoming helplessness
- Session 11: Moving beyond grief
- Session 12: Healthy social relationships

Format: To address the psychiatric and neuropsychological needs that are often present in clients who are dealing with substance abuse issues, the sessions of HHRP are presented using

multiple teaching approaches so all persons can learn, regardless of learning style. These strategies include:

- 1) Multimodal presentation of materials including verbal (lectures and discussion), visual (slides, videos, charts, and written material), and skills-building (games, practice, role-plays) modalities.
- 2) Frequent reviews to facilitate learning and retention.
- 3) Reduction of the fatigue and distraction which impede learning and may be particularly problematic for cognitively impaired clients. Frequent breaks, multimodal presentations, and minimizing outside noise/distractions help to improve concentration and achieve this goal.
- 4) Provide consistency by meeting at the same time and place each week, providing an agenda, and following the same structured format.
- 5) Assessment and feedback regarding knowledge and skills gained. This allows members to evaluate the different learning and teaching strategies and also provides a chance for additional practice of new skills.
- 6) Generalizability of information presented to the life situations of group members.
- 7) Memory book system to improve memory for session material and for organizing and remembering activities required for living a healthy lifestyle.
- 8) Learning by doing through activities that are appropriate to the group topic and aid in skills acquisition, retention, and self-confidence. Immediate feedback during games can reinforce appropriate behaviors, discourage less helpful behaviors, and increase self-esteem and self-confidence.
- 9) Management of stress through visualization strategies focused on relaxation and health promotion. Stress can impair concentration, increase cognitive dysfunction (such as memory difficulties or impulsivity), and potentially lead to relapse.
- 10) Group treatment modality to permit generalizable pro-social behaviors to be practiced and strengthened. This can reduce feelings of isolation and provide a sense of interpersonal support from individuals with similar life circumstances.

Counselors: HHRP groups are optimally co-facilitated by two substance abuse counselors with experience working with HIV-positive substance abusers and are comfortable with the concept of harm reduction in this population. A male/female team is recommended. The two counselors work as a team to facilitate all aspects of the groups, but one is primarily responsible for assuring that all material is presented in accordance with the manual, while the second is primarily responsible for experiential aspects of the group. Counselors must establish group structure, provide a consistent model of behavior and behavior change, and employ a consistent non-

judgmental therapeutic style to assist the client in reaching his/her own harm reduction goals. The HHRP manual furnishes counselors with all the materials they will need to provide the intervention with a minimal amount of training necessary (i.e., detailed scripts are available for each group session and all necessary visual aids [slides or PowerPoint format], learning activities, and quizzes. HHRP counselors should receive on-going supervision from a clinically trained professional with experience in harm reduction.

Mechanism of Behavior Change: The HHRP takes a harm-reduction approach to behavior change in which abstinence from drug use or sexual risk-taking behavior is one goal along a continuum of risk-reduction strategies. Clients are not assumed to be abstinent from either drug use or sexual risk behaviors. Risk behaviors are viewed as being sustained by hopelessness in the face of a life-threatening illness, high levels of stress, psychiatric disorders, and medical and social problems. In addition, the ability to acquire and retain the skills needed for change is impeded by HIV- and drug-related cognitive deficits. By presenting materials in such a way as to minimize the effects of cognitive difficulties, and providing clients with an empathic, directive, non-confrontational setting in which structure and consistency are emphasized, the HHRP intervention allows clients to meet their own harm-reduction goals.

RESOURCE REQUIREMENTS

To provide HHRP to up to 12 HIV-positive individuals, an agency will need two experienced counselors for each two-hour group session. We estimate that each counselor will need to receive between 12-24 hours of training in HHRP prior to conducting the intervention. An agency will also need audio-visual equipment, such as a slide projector and screen (or PowerPoint projector and screen), a TV/VCR with remote control, and easel, easel chart paper, and markers. Funds will also be needed for small prizes (valued at \$5-10) that are awarded at each group session.

RECRUITMENT

The original HHRP intervention was offered to clients in a methadone maintenance clinic. The intervention can be adapted to reach clients in any drug treatment program, or in a community-based organization (CBO) serving a high percentage of PLWH with substance abuse and dependence issues. Agencies wishing to implement HHRP should review the Procedural Guidance for Recruitment (see p. 11) in order to choose a recruitment strategy that will work in the setting in which they plan to implement HHRP.

PHYSICAL SETTING CHARACTERISTICS

This intervention is most appropriate for a facility that treats clients with substance abuse/dependence issues. It can be implemented in a methadone maintenance or other drug treatment facility or in a CBO serving a high percentage of drug using, HIV-positive clients. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room, or outside noise levels.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement HHRP the following policies and procedures should be in place to protect participants, the agency, and the HHRP program team:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in HHRP, clients will be disclosing their HIV status. With that in mind, agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Prevention Case Management, Partner Counseling and Referral Services, Health Department/Community-based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both facilitators and participants should be in place when implementing HHRP:

Facilitator: The HHRP manual is comprehensive and contains detailed scripts for each session. Additional training required for facilitators will depend upon the facilitator's level of expertise, but could include the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practice with mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. Quality assurance activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of multimodal presentation of material; use of role-play; use of behavioral games as teaching aids, and comfort with the non-judgmental, non-confrontational approach to treatment. Weekly supervision should ensure that treatment is provided in accordance with the HHRP manual, that ways to adapt the manual are discussed, and that process counselor concerns are shared. Selected intervention record reviews should focus on assuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at each session.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.

- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
 - **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
 - **III.C-** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
 - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.

KEY ARTICLES AND RESOURCES

¹Margolin A, Avants SK, Warburton LA, Hawkins KA, Shi J. (2003). A randomized clinical trial of a manual-guided risk reduction intervention for HIV-positive injection drug users. *Health Psychology*, 22(2) 223-228.

²Copenhaver M, Avants SK, Margolin A, Warburton LA. (2003). Intervening effectively with drug abusers infected with HIV: Taking into account the potential for cognitive impairment. *Journal of Psychoactive Drugs*, 35(2), 209-218.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). *Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators*.

Intervention materials including background information, and research, as well as manuals and instructional materials for individual and group sessions are available for download by clicking on the Training link at <http://www.3-s.us/>.

CDC would like to acknowledge and thank the faculty and staff of the Harm Reduction Unit, Division of Substance Abuse, Department of Psychiatry, Yale University School of Medicine for their assistance in compiling this Procedural Guidance for Implementation of the Holistic Harm Reduction Program.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF HEALTHY RELATIONSHIPS

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF HEALTHY RELATIONSHIPS

Healthy Relationships¹ is a 5-session, small-group intervention for men and women living with HIV/AIDS. It is based on Social Cognitive Theory and focuses on developing skills and building self-efficacy and positive expectations about new behaviors through modeling behaviors and practicing new skills. An intervention package, training, and technical assistance on the Healthy Relationships intervention will be available from CDC in July 2004.

The intervention addresses building skills to reduce stress in three life areas: disclosure of HIV status to family and friends, disclosure to sex or needle sharing partners, and adoption of safer sexual behaviors. Decision-making and problem-solving skills are developed to enable the participants to make informed and safe decisions about disclosure and behaviors. In each of the three life areas, a series of exercises is repeated to create and develop decision-making and problem-solving skills. The primary exercise is role-playing based on scenarios that are established by viewing short clips from popular movies. The intervention is adaptable to different populations by varying the choice of movie clips and providing flexibility in implementing role plays to allow for cultural influences. Healthy Relationships is intended to create a positive, engaging, and creative atmosphere that can be integrated into existing support groups or can be introduced as a new program.

Compared to a health maintenance control group, participants in the Healthy Relationships intervention group reported greater self-efficacy for suggesting condom use with new sex partners and being able to satisfy sex partners and themselves even when practicing safer sex. Participants also reported intentions to consider the pros and cons of HIV status disclosure to partners and to engage in safer sex with partners who did not know their HIV status. At 3-month and 6-month follow-up contacts, intervention group participants were significantly more likely than the control group to have followed through on their earlier intentions and to have considered the pros and cons of HIV status disclosure to sex partners. At the 6-month follow-up the intervention group participants were significantly more likely to have refused to engage in unsafe sex (which was not true at the 3-month follow-up). The intervention group participants also reported less unprotected intercourse, more protected intercourse, and fewer sexual contacts than the control participants at the 6-month follow-up. Furthermore, they had less sexual intercourse and less unprotected intercourse with non-HIV-positive partners at both the 3- and 6-month follow-ups. These results demonstrate that this intervention is broadly applicable across subpopulations, including persons of different sexual orientations, with a history of incarceration,

current or past drug use, or psychiatric history, and indicates a long-term effect (at least up to 6-months) on both reported behaviors and perceived self-efficacy.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Healthy Relationships has 5 core elements which include:

- 1) Defining stress and reinforcing coping skills with HIV-positive people across three life areas:
 - a. disclosing to family and friends,
 - b. disclosing to sexual partners,
 - c. building healthier and safer relationships.
- 2) Using modeling, role-play, and feedback to teach and practice skills related to coping with stress.
- 3) Teaching decision-making skills around the issue of disclosure of HIV status.
- 4) Providing participants with personal feedback reports to motivate change of risky behaviors and continuance of protective behaviors.
- 5) Using popular movie clips to set up scenarios around disclosure and risk reduction to stimulate discussions and role-plays.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Healthy Relationships has 9 key characteristics:

- Participants meet in small groups, similar in style to support groups. New members cannot join once the series of sessions has begun.
- Participants sit in a circle, face-to-face.
- Participants meet for at least five, 120-minute sessions.
- Groups contain members of the same gender and sexual orientation.
- At least one group facilitator is an experienced and skilled counselor, preferably a mental health professional. This facilitator may or may not be HIV-positive.
- The peer facilitator should be HIV-positive.*
- One facilitator is male and the other female.*
- At least one facilitator matches the ethnicity of the majority of the participants.*

- Both facilitators need the personal characteristics and group skills of effective facilitators.

* These particular key characteristics bring immediate credibility and rapport with group participants.-

Procedures describe the activities that make up the content of the intervention and provide direction to agencies or organizations regarding the implementation of the intervention. Procedures for Healthy Relationships follow.

Healthy Relationships is based on interactive sessions that educate and engage participants. They are not classes, lectures, or forums. These sessions create a context where people can interact, examine their risks, develop skills to reduce their risks, and receive feedback from others.

Groups consist of 5 to 12 people of similar backgrounds. Participants sit in a circle so that they can easily see each other, share experiences, practice new skills, and receive feedback from their peers. Two facilitators, one of whom is an HIV-positive peer, use easel chart guides to lead participants through the Healthy Relationships content.

Each participant completes an initial assessment survey. From this survey three personal feedback report (PFR) forms are created for each participant from their initial assessment survey interview. These PFR forms are designed to reinforce participants' motivation to change by helping them identify their behaviors, as well as which behaviors they want to change and which they want to maintain. The PFR forms are distributed in three different sessions, each one tied to one of the life areas mentioned in core element number one.

Three risk continuum exercises occur after each PFR is distributed and discussed. The continuum exercises use a long banner with a double-ended arrow labeled from high to low. The line of the arrow and the cards have corresponding pieces of Velcro fasteners on their backs to allow them to be attached and detached easily from the banner.

The continuum banner is used in three of the sessions, each time with a different set of cards. These exercises focus on how the participants view each of the following:

- Exercise 1: risk/stress of disclosure to family and friends
- Exercise 2: risk/stress of disclosure to sexual partners
- Exercise 3: risk of various sexual behaviors

Participants attach the cards given to them based on their personal evaluation of the stress or risk involved.

There are a variety of videos and movie "clips" shown in the five sessions of Healthy Relationships: personal statements, HIV/AIDS information, condom demonstration, and, most importantly, segments from popular movies. The term clip is used, regardless of whether the clip is short or long or even an entire video. Facilitators give brief descriptions or scenarios to introduce clips while tying them to the objectives of that session. Correctly setting up the scenarios facilitates both role-playing and discussion. These scenario descriptions are also used on many of the easel chart guides.

RESOURCE REQUIREMENTS

To conduct Healthy Relationships, an agency will need a 100% full-time equivalent (FTE) paid, experienced counselor, one 25% FTE peer facilitator (volunteer or paid) for each population of people living with HIV (PLWH) (e.g., women, heterosexual men, MSM) for whom Healthy Relationship sessions will be offered, and one 25% FTE program manager for evaluation and quality assurance. We estimate that each counselor and peer facilitator will need to attend at least 24 hours of training in Healthy Relationships. An agency will need from 40 to 60 hours to find and assemble 13 video/movie clips to use during the sessions (4 video clips will be provided in the intervention package). The actual number of hours and costs for assembling the clips depends on 1) staff knowledge of movies and appropriate clips, 2) equipment access and staff skill to assemble clips on a VCR tape or DVD disk or contract for these services, and 3) the number of populations of PLWH who will be receiving the intervention (most of the selections are population-specific). An agency will need to acquire, if they do not already own, a TV/VCR with remote control or a DVD player with remote control. The intervention also involves the use of an easel, easel chart paper, and markers. Small incentives may be used to encourage participation, and one small prize may be given away through a random drawing at the end of each session.

RECRUITMENT

The following recruitment strategies can be used to reach PLWH:

- Recruit from support groups.
- The Healthy Relationships package comes with generic marketing tools including a video and printed promotional literature that can be modified for specific populations.
- Send press releases to local radio and TV stations.
- Advertise in local newspapers, including gay and alternative papers.
- Post announcements on the Internet.

Agencies wishing to implement Healthy Relationships should review the Procedural Guidance for Recruitment in this document in order to choose a recruitment strategy that will work in the setting in which they plan to implement Healthy Relationships.

PHYSICAL SETTING CHARACTERISTICS

In order to select sites to perform Healthy Relationships, agencies should first consider the sites' capacity to provide audio and visual equipment, specifically a TV and VCR or DVD player with a remote control. The intervention sessions must be conducted in a private and secure location so that confidentiality of participants can be maintained. It is crucial that intervention sessions are not interrupted by distractions such as people entering and exiting the room or outside noise levels. Not all of the intervention participants will have disclosed their HIV status and may not feel comfortable with others knowing; therefore, the intervention site should be at a discrete location.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement Healthy Relationships, the following policies and procedures should be in place to protect participants, the agency, and the Healthy Relationships intervention team:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in easily understandable language the agency's responsibility and the participants' rights. Individual state laws apply to consent procedures for minors, but at a minimum consent should be obtained from each participant and/or a legal guardian if the participant is a minor or unable to give legal consent. Client participation must always be voluntary and documentation of this informed consent must be maintained in the client's record.

Legal/Ethical Policies: It is important to keep in mind that by virtue of participation in Healthy Relationships, clients will be disclosing their HIV status. With that in mind, agencies must know their state laws regarding disclosure of HIV status to sexual and/or needle-sharing partners, and agencies are obligated to inform participants of the potential duty warn and the agency's responsibility. Agencies also must inform participants about state laws regarding the reporting of domestic violence, child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to session participants, as necessary. Providers must know about referral sources for prevention interventions/counseling (Prevention Case Management, Partner Counseling and Referral Services, Health Department/Community-based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for both facilitators and participants should be in place when implementing Healthy Relationships:

Facilitator: Training for facilitators should address the following three areas: (1) completion of a training workshop, including review of the intervention theory and materials; (2) participation in practice sessions; and (3) observed co-facilitation of groups, including practicing mock intervention sessions. Agencies should have in place a mechanism to ensure that all session protocols are followed as written. Quality assurance activities can include observation and review of sessions by key staff and supervisors involved with the activity. This review should focus on adherence to session content, use of appropriate videotapes with adequate facilitation of discussions, accessibility and responsiveness to expressed participant needs, and important process elements (e.g., time allocation, clarity). Selected intervention record reviews should focus on ensuring that consent forms (signed either by the participant if he/she is over 18 or emancipated, or by a legal guardian) are included for all participants, and session notes are of sufficient detail to ensure that clients are participating actively.

Participant: Participants' satisfaction with the intervention and their comfort should be assessed at each session.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:

- **III.A-** Proportion of persons living with HIV, their sex partners and injection drug-using contacts who are HIV negative or who do not know their HIV status who completed the intended number of sessions for each of the prevention interventions supported by this program announcement.
- **III.C-** Percent of HIV infected persons who, after a specified period of participation in each of the prevention interventions supported by the program announcement, report a reduction in sexual or drug-using risk behaviors or maintain protective behaviors with seronegative partners or with partners of unknown status.
- **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information

KEY ARTICLES AND RESOURCES

¹Kalichman SC, Rompa D, Cage M, DiFonzo K, Simpson D, Austin J, Luke W, Buckles J, Kyomugisha F, Benotsch E, Pinkerton S, & Graham. Effectiveness of an intervention to reduce HIV transmission risks in HIV-positive people. *American Journal of Preventive Medicine* 2001;21(2):84-92.

U.S. Department of Health and Human Services, OPHS Office of Minority Health. (2001). *National Standards for Culturally and Linguistically Appropriate Services in Health Care*.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). *Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators*.

An intervention package, training, and technical assistance on the Healthy Relationships intervention will be available from CDC starting in July 2004.

CDC would like to acknowledge and thank the faculty and staff of the Dallas STD/HIV Prevention Training Center for their assistance in compiling this Procedural Guidance for Implementation of Healthy Relationships.